Food and Drug Administration
Center for Biologics Evaluation and Research
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Silver Spring, MD 20993-0002

To: Administrative File BLA STN 125771/0

From: Gregory Price, DMPQ CMC Reviewer, OCBQ/DMPQ/MRB3

Through: CDR Donald Ertel, Branch Chief, OCBQ/DMPQ/MRB3

CC: Niloofar Kennedy, RPM, OTAT/DRPM/RPMB3
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Carolyn Renshaw, Division Director, OCBQ/DMPQ
Jie He, Team Lead, OCBQ/DMPQ/MRB3

Applicant: Bioverativ Therapeutics Inc.; US License # 2078

Product: Altuviiio (efanesoctocog alfa)

Indication: Treatment of Hemophilia A

Subject: Inspection Waiver for Pre-License Inspections (PLI) of manufacturing facilities listed herein.

Due Date: February 28, 2023

Recommendation: To waive PLI of the facilities described herein.

The following information provides justification to support the waiver recommendation:

1) Inspection History

Location	Activity	Most Recent Inspection
(b) (4)	Altuviiio Drug Substance (DS) manufacture and storage, DS release testing and release	CDER (b) (4) Voluntary Action Indicated (VAI)
	Sterile water for injection (sWFI) manufacture, visual inspection, quality control testing	ORA (b) (4) No Action Indicated (NAI)

Location	Activity	Most Recent Inspection
(b) (4)		
(b) (4)	Altuviiio DS and Drug Product (DP) release testing	ORA (b) (4) NAI
	Altuviiio DP release testing	ORA (b) (4) NAI
	DP Diluent (sWFI) release testing	CDER (b) (4) VAI
	DP Diluent (sWFI) release testing	CDER (b) (4) VAI
	Altuviiio DP primary labelling and packaging	ORA (b) (4) NAI
	Altuviiio DP primary labelling and packaging	MRA inspection review by ORA (b) (4) VAI

2) For the subject BLA (Biologic License Application), the facilities proposed for this inspection waiver are currently approved to perform their respective significant manufacturing steps with the same equipment for other approved and/or other licensed products.

   The (b) (4) facility for Altuviiio DS manufacturing was recently inspected by the CDER/FDA in (b) (4) with an acceptable VAI outcome.

   The most recent FDA inspection of the (b) (4) facility in (b) (4) was performed in (b) (4) by ORA/FDA with an acceptable NAI outcome. This facility only manufactures sWFI diluent for the

subject BLA and uses dedicated or single-use equipment for this process. All single use sWFI filled syringes undergo (b) (4)

The DP and DP diluent (sWFI) release testing and labelling facilities listed in the table above are approved for these manufacturing steps and have acceptable compliance records from recent inspections.

3) For the subject BLA, the DS and DP diluent (sWFI) are produced in established facilities as presented in the table above. There are no new buildings nor changes to equipment or utilities being reported for either facility following those recent inspections. The (b) (4) facility will be utilized for cell culture manufacture of Altuviiio, purification, formulation and filling utilizing equipment used to manufacture other FDA-approved products.

Concurrence Signatures:

Zuben Sauna
Chair/Product CMC Reviewer
Division of Plasma Protein Therapeutics
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research _____

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